OPERATION MANUAL

Contra Angles

Ti-Max X

FX series

NSK

CE 0197

MADE IN JAPAN

1 Preface

1–1 User and intended purpose

User	:	X35L / X35 / FX75 / FX75m / FX74m / FX70m Qualified Professionals (Dentist) X55L / X55 / X57L / X57 / FX57 / FX57m / FX58m / FX55m / FX50m Qualified Professionals (Dentists and dental hygienist)
Intended purpose	:	X35L / X35 / FX75 / FX75m / FX74m / FX70m The dental handpiece is intended for the following application(s): Root canal preparation X55L / X55 / X57L / X57 / FX57 / FX57m / FX58m / FX55m / FX50m The dental handpiece is intended for the following application(s): Removal of accretions and deposits from the surface of teeth and dental restorations (fillings and prostheses), and polishing of the surface of teeth and dental restorations.
Patient population	:	Any patient (ages 2 and over). The user's discretion is required prior to use.

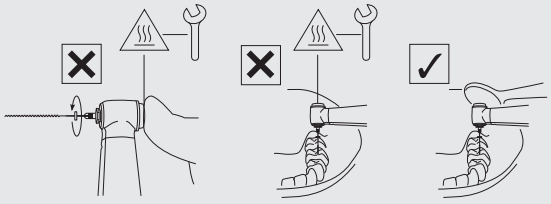
1–2 Precautions for handling and operation

■ Please read these precautions carefully and use only as intended or instructed.
■ Safety instructions are intended to avoid potential hazards that could result in personal injury or damage to the device. Safety instructions are classified as follows in accordance with the seriousness of the risk.

Class	Degree of Risk
⚠ WARNING	Hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.
⚠ CAUTION	Hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
NOTICE	General product specification information highlighted to avoid product malfunction and performance reduction.

⚠ WARNING

- Depressing the Push Button while the handpiece is in rotation may lead to overheating, causing burn injuries or product failure. Avoid the push button to contact with any oral tissue. (Except for X55L / X55 / X57L / X57 / FX57 / FX57m / FX58m / FX55m / FX50m)
- Use polishing paste only when using Prophy handpiece with X57L / X57 / FX57 / FX57m / FX58m. When polishing paste is used other handpieces, the polishing paste could enter the handpiece, causing failure of the ball bearings or burn injuries due to the overheating of the handpiece head.
- Keep any debris or other foreign materials away from inside the gear or the handpiece. Foreign materials remaining inside may lead to overheating, causing burn injuries or other accidents.
- Ball bearings are wear-and-tear items and may require replacement. Be sure to inspect the handpiece before use. If abnormal vibration or noise are found, the bearings or other internal parts may be worn out or damaged. Damaged parts may lead to handpiece overheating causing burn injuries. If overheating is suspected, stop using the handpiece immediately and contact your Authorized NSK Dealer.



⚠ CAUTION

- When operating the product always consider the safety of the patient.
- Users are responsible for the operational control, maintenance and continual inspection of this product.
- Do not disassemble or alter the handpiece and cartridge, etc. except as recommended by NSK in this Operation Manual.
- Should the handpiece function abnormally during use, stop using the handpiece immediately and contact your Authorized NSK Dealer.
- The product is delivered in a non-sterile condition. Be sure to sterilize the product prior to use.

Preface

⚠ CAUTION

- Follow the specifications described in this operation manual as to the file/reamer/rubber cup/brush/Tip(EVA)/Prophy handpiece to be used, etc. to prevent accidental release or breakage of the file/reamer/rubber cup/brush/Tip(EVA)/Prophy handpiece during rotation.
- Perform regular function and maintenance checks.
- To avoid clinical downtime it is recommended that a spare be kept on hand in case of a breakdown during surgery.
- The operation of the handpiece is permitted only on dental units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- Contact your Authorized NSK Dealer if repairs are necessary.
- Please report any serious incident that may occur in connection with this product and its accessories to the manufacturer as well as to your national authority.
- Do not exceed the Max. Rotation Speed (Motor) shown in the specifications in this operation manual.
- Only connect/disconnect the handpiece or file/reamer/rubber cup/brush /Tip(EVA)/Prophy handpiece when the handpiece has stopped.
- Do not apply excess pressure to the file/reamer/rubber cup/brush /Tip(EVA)/Prophy handpiece as it may break or bend and become difficult to remove. Doing so may also cause burn injury due to abnormal heating.
- Always follow the instructions provided by the file/reamer/rubber cup/brush manufacturer regarding the file/reamer/rubber cup/brush / handpiece for usage and rotation speed, etc.

X35L / X35 / FX75 / FX75m / FX74m / FX70m

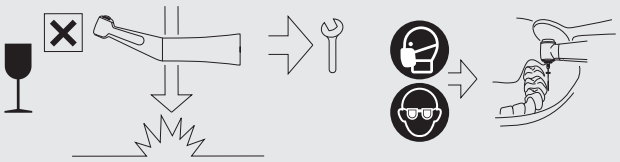
- When you work on root canal expansion, DO NOT set the drive source (Motor) speed other than the values that written on the “SPECIFICATION”. Follow the maximum rotation speed that file or reamer manufacturer recommends.
- Follow the package insert from the file/reamer manufacturer.
- Do not use bent, damaged, or sub-standard files or reamer. The shank could bend or break even within the recommended speed.
- Always keep the file, reamer shank clean, Entry of debris into the chuck cause file or reamer run-out and the file or reamer could not be mounted inmost.
- DO NOT exceed the maximum permissible rotation speed that manufacturer recomend.
- Do not use the file, reamer or shake shape other than ISO 1797(EN ISO 1797) standards.(Except Hand file)
- File may change (throwaway) every patient or several times. If it used several time, it may cause a fracture by metal fatigue.

X57L / X57 / FX57 / FX57m / FX58m

- Wash the handpiece immediately after use. Failure to wash the handpiece may lead to abrasive paste to become fixed inside and may cause failure. abrasive paste may fix inside and it may cause a failure.
- DO NOT use the rubber cap which the screw does not match.
- Do not use above the specified rotational speed. This could cause in injury or accident by flying paste or broken cup and brush.
- Do not use in the reverse rotation. The cup and brush could fly out of the head.

X55L / X55 / FX55m

- Metallic shank cannot be used.



NOTICE

- Substances which are carcinogenic, mutagenic or toxic to reproduction (‘CMR’), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5 of Regulation (EU) No 528/2012 of the European Parliament and the Council, in accordance with the criteria that are relevant to human health amongst the criteria established therein: lead (Pb), cobalt (Co).
  - This product can be safely used in the treatment of children, pregnant or breastfeeding women, or other patient groups considered particularly vulnerable to such substances.

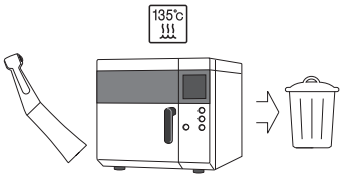
1–3 Symbol

	Move in the direction indicated.		Move fully to the stop, in the direction indicated.
	Prohibited / Process NOT permitted / Wrong		Do the step / Process permitted / Correct
	If...(Hypothetical situation)		Listen (Clicking sound)
	State of being fixed.		Call for maintenance
	Wear protective gloves		Wear a face mask
	Wear eye protection		Temperature
	Ultrasonic bath		The instrument can be used with a washer-disinfector for thermal disinfection.
	This product can be sterilized in a steam sterilizer at 135°C.		Drying time
	Lamp / lighting / illumination		Drinkable tap water
	Visual check		Do not use any object with a sharp edge.
	Caution, hot surface		Consult operation instructions
	Conforms to CE European Regulation of "Medical Device Regulation"		Manufacturer
	Importer for Europe		Authorized representative in the European Community
	Authorised representative for Switzerland		Medical Device
	Catalog number (Order code)	MODEL:	MODEL:
	Serial No.		Date of manufacture
	Unique Device Identifier		GS1 DataMatrix for Unique Device Identifier.
	Contains hazardous substances		Use Environment

	Transportation and Storage Environment		Recommend
	Water Pressure		Chip Air Pressure
	Temperature limitation		Humidity limitation
	Atmospheric pressure limitation		Keep away from sunlight
	Keep dry		Fragile / handle with care
DURA GRIP	NSK original surface treatment		

1–4 Disposing of products

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When your medical device has reached the end of its service life, it must be disposed of via a specialist collection, removal, recycling or destruction channel. Prior to doing so, in order to avoid the health risks to operators handling the disposal of medical equipment, as well as the risks of environmental contamination caused thereof, you need to confirm the equipment is decontaminated.
Therefore contact your nearest NSK dealer, or one of the NSK branches to find out how to proceed.
Refer to the link below:

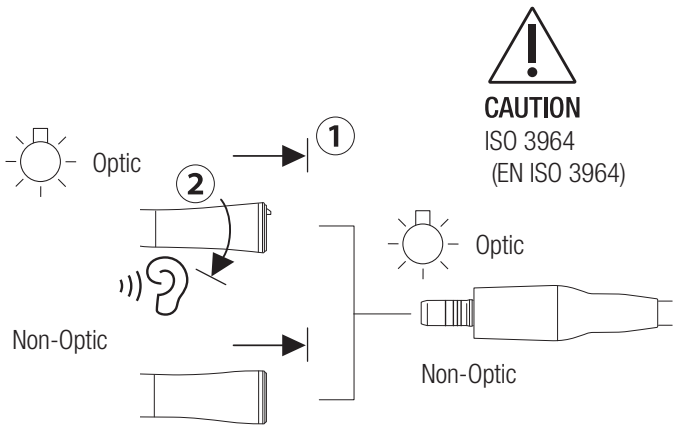
1–5 Warranty

NSK products are warranted against manufacturing errors and defects in materials. NSK reserves the right to analyze and determine the cause of any problem. Warranty is voided should the product be not used correctly or for the intended purpose or has been tampered with by unqualified personnel or has had non NSK parts installed. Replacement parts are available for seven years beyond discontinuation of the model.

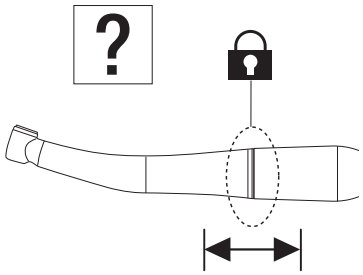
2 Preparation for Use

2–1 Mounting the handpiece

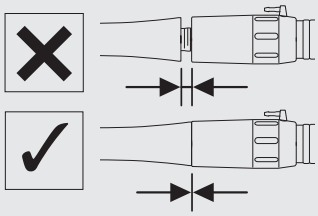
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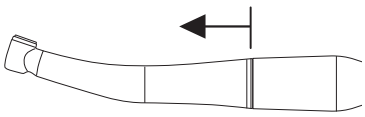


⚠ CAUTION

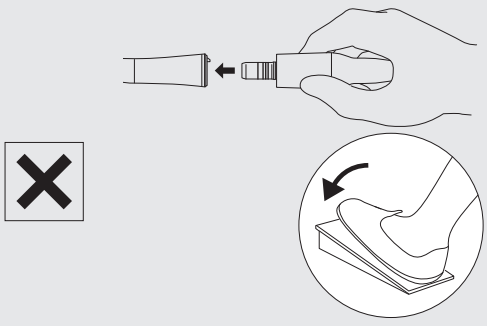


2–2 Removing the handpiece

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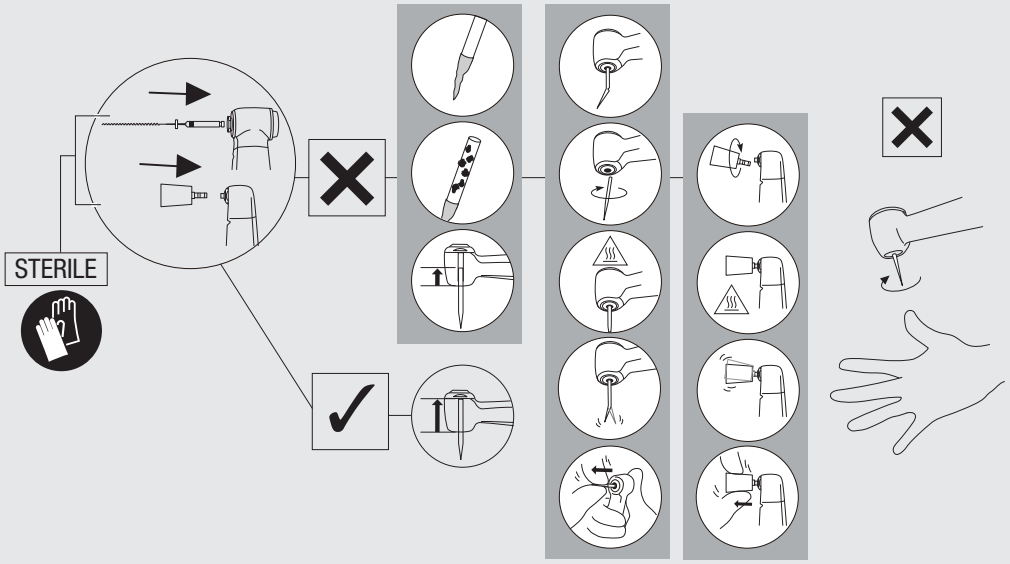
⚠ CAUTION



2–3 Mounting/Removing the file/tip/cup/brush/Prophy handpiece

⚠ WARNING

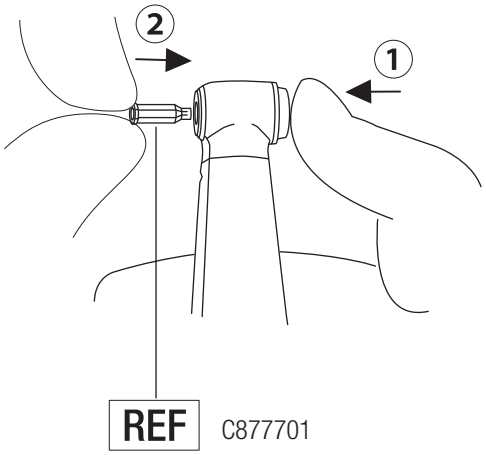
- If blood or debris is stuck, wipe in and around the file/reamer/rubber cup/brush insertion hole with a cloth moistened with disinfectant solution until all residues are thoroughly removed. Residual blood or debris may enter the handpiece while changing burs, which could lead to higher risk of cross-contamination.



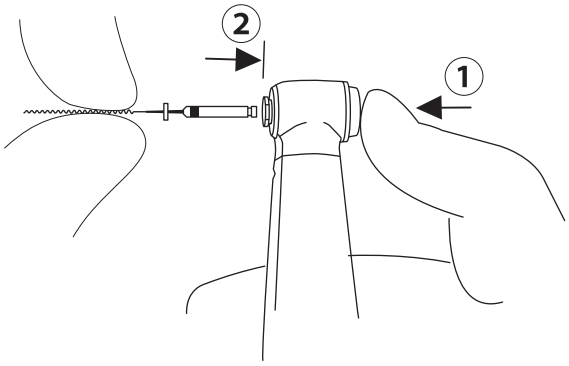
2–3–1 Mounting the Engine File

X35L / X35

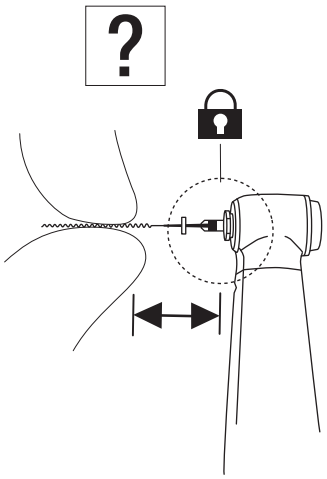
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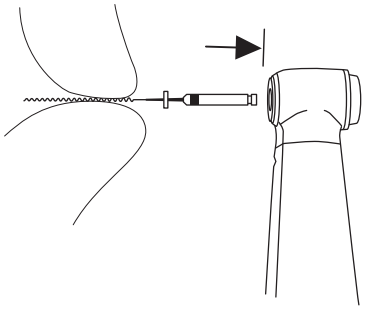


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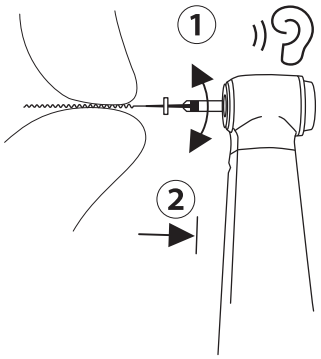


FX74m / FX75 / FX75m

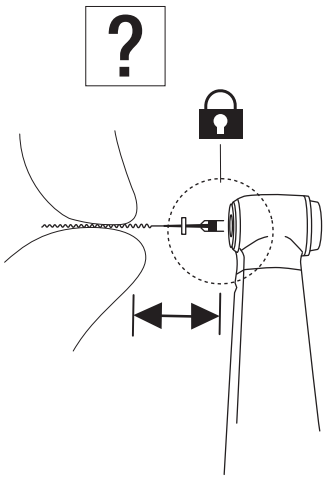
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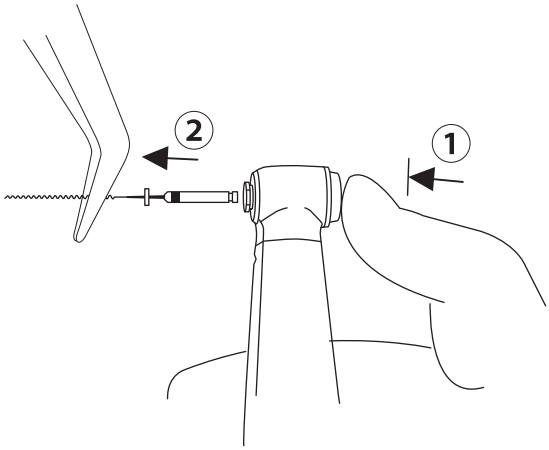
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2–3–2 Removing the Engine File

X35L / X35 / FX74m / FX75 / FX75m

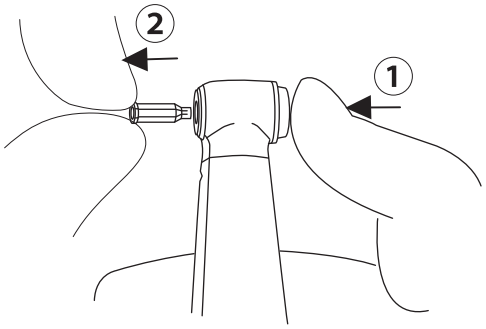
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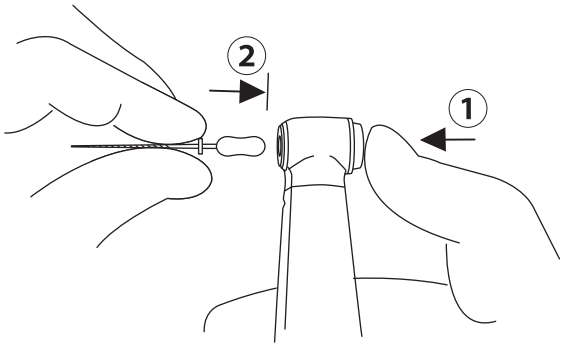
2–3–3 Mounting the Hand File

X35L / X35

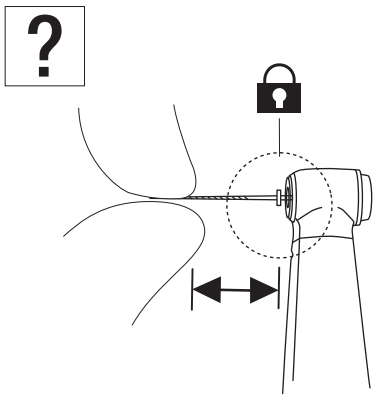
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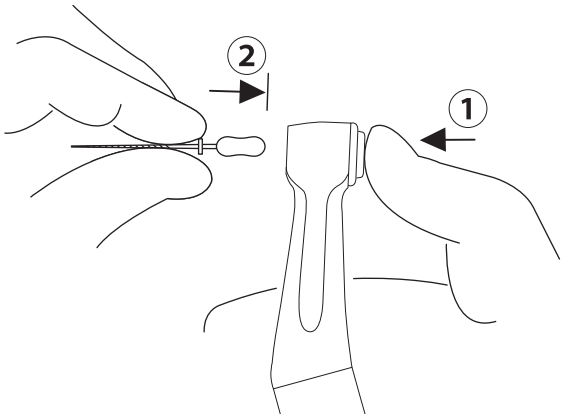


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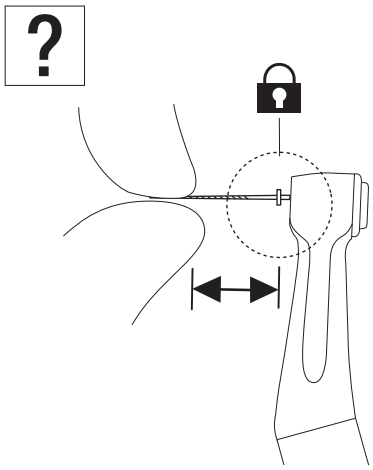


FX70m

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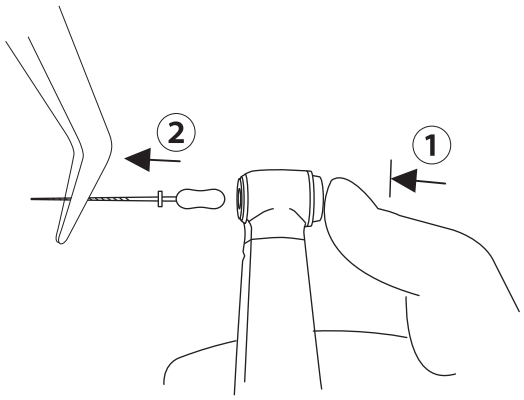
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2–3–4 Removing the Hand File

X35L / X35 / FX70m

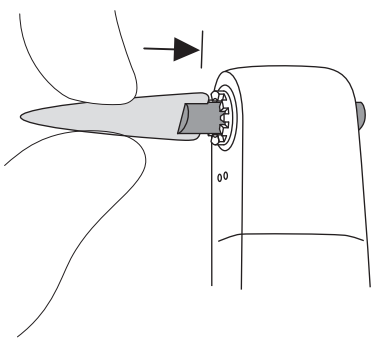
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2–3–5 Mounting the Eva tip / Profin tip / Orthodontics file

X55L / X55 / FX55m

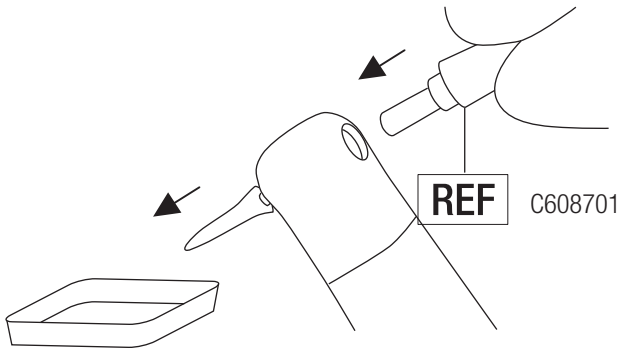
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2–3–6 Removing the Eva tip / Profin tip / Orthodontics file

X55L / X55 / FX55m

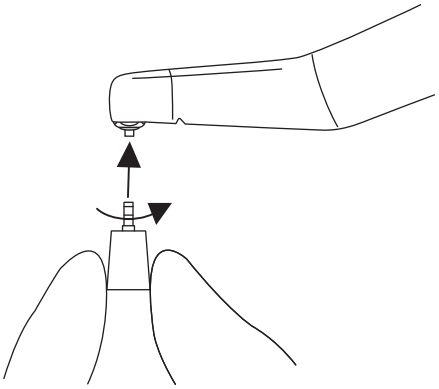
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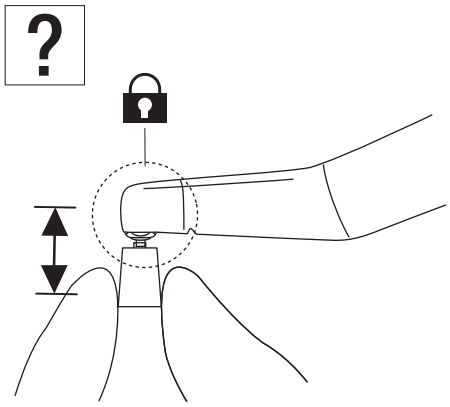
2–3–7 Mounting the Prophy cup/brush

X57L / X57 / FX57 / FX57m

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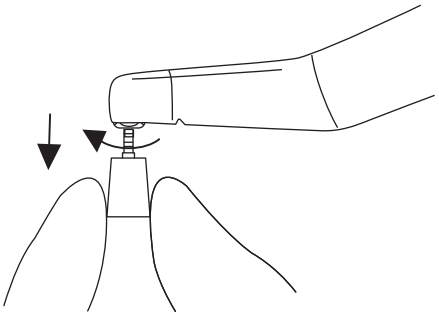
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2–3–8 Removing the Prophy cup/brush

X57L / X57 / FX57 / FX57m

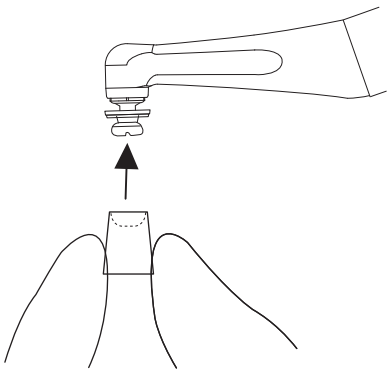
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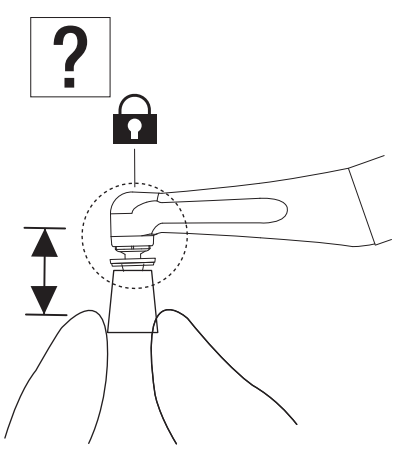
2–3–9 Mounting the Prophy cup

FX58m

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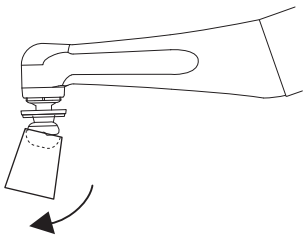
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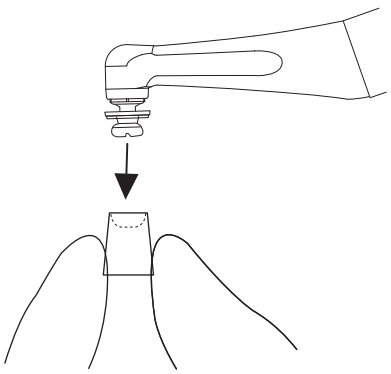
2–3–10 Removing the Prophy cup

FX58m

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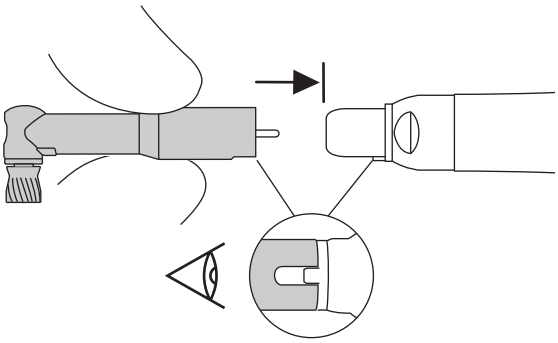
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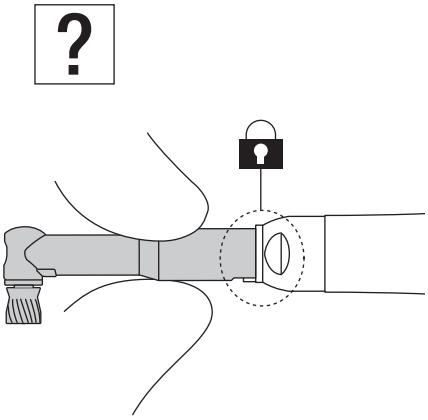
2–3–11 Mounting the Prophy handpiece

FX50m

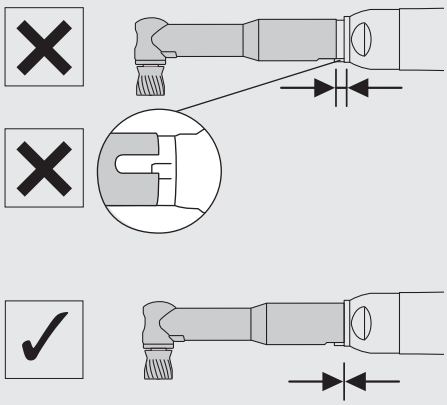
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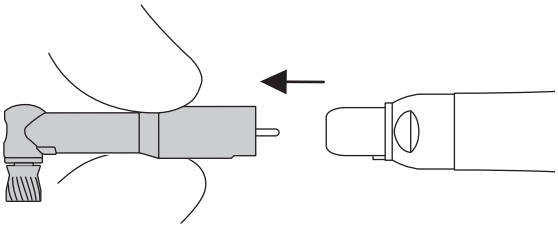
⚠ CAUTION



2–3–12 Removing the Prophy handpiece

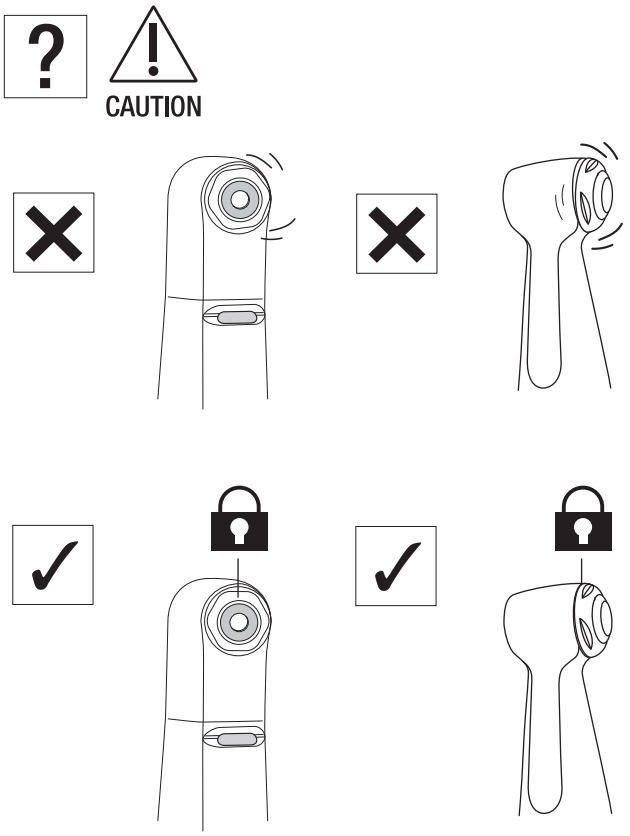
FX50m

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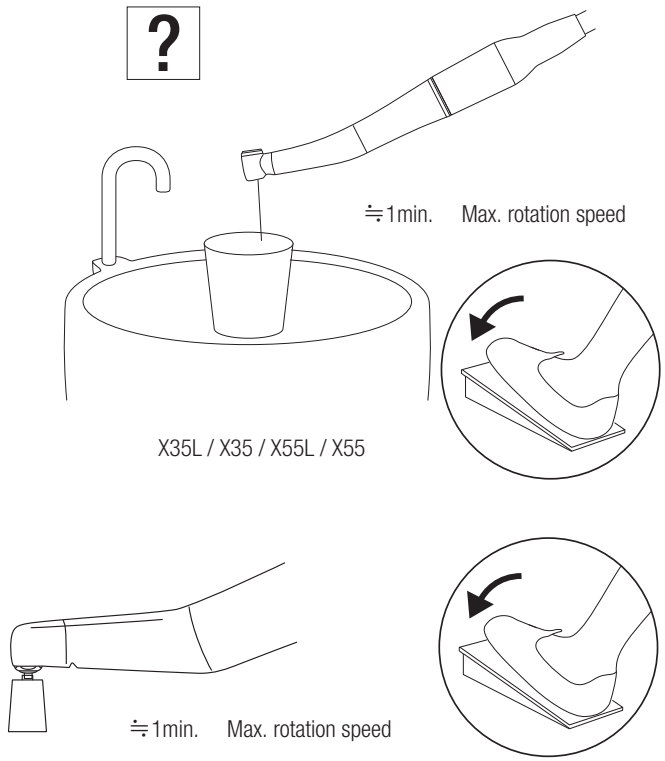


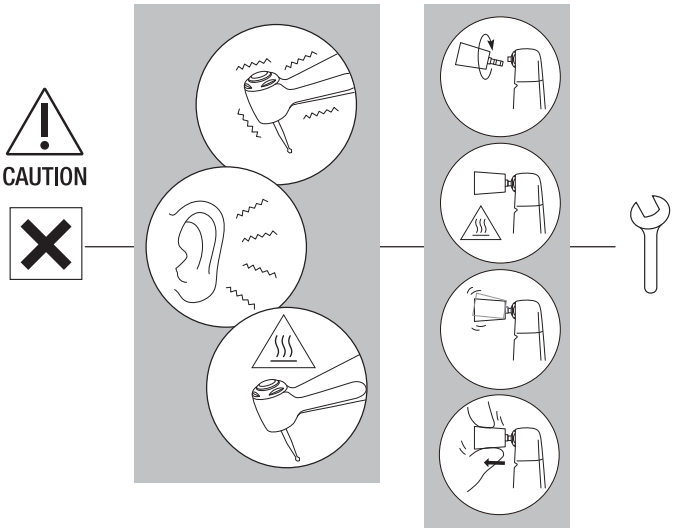
2–4 Check before treatment

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3 Post-use Maintenance

⚠ WARNING

- To ensure cleaning and sterilization efficacy, use only the following procedures for reprocessing.
- Always obey the local directives, standards, guidelines, etc., as to the cleaning, disinfection, and sterilization of the product.
- Failure to properly maintain the products may cause infection, product failure, or overheating and injuries. Be sure to clean and disinfect the products immediately (within 1 hour) after use to remove residue.
- If blood infiltrates inside a handpiece, an automatic handpiece cleaning and lubrication system may not totally clean the internal handpiece components and may lead to blood coagulation inside the handpiece. Coagulated blood may cause handpiece failure and overheating, causing burn injuries. To avoid the risk, NSK recommends to immediately lubricate those handpieces with PANA SPRAY Plus.

⚠ CAUTION

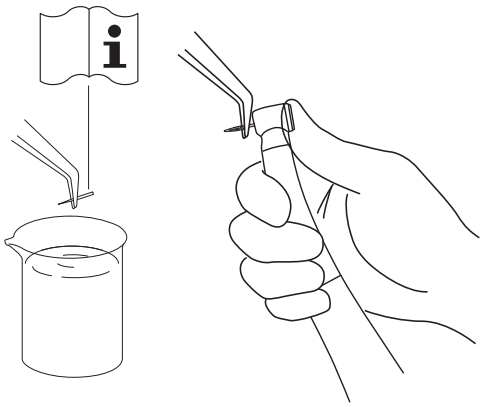
- Do not use solvents such as electrolyzed-oxidizing water (strong acidic water or super acidic water), strong acidic or alkaline chemical, chlorine-containing solvent, benzine and thinner when cleaning, immersing, or wiping.
- After the thermo disinfection, take the product out of the washer-disinfector immediately (within an hour). Failure to do so causes corrosion.
- After using the washer-disinfector, dry the product completely, because remaining moisture may cause internal corrosion, etc.
- Do not use sprays other than NSK PANA SPRAY Plus. Using other sprays may cause handpiece overheating.
- Clean and lubricate the handpiece prior to sterilization. If blood remains on the internal surface, it may become clotted and cause product failure.
- Immediately after sterilization is complete (within 1 hour), remove the handpiece from the sterilizer. Failure to do so may cause corrosion.
- Do not perform steam sterilization on the product with other instruments even when it is in a pouch. This is to prevent possible discoloration and damage to the product from chemical residue on other instruments.
- Sterilization is not guaranteed after the sterilization retention period specified by the manufacturer and seller of the sterilization pouch has elapsed. If the sterilization retention period has elapsed, perform sterilization again with a new sterilization pouch.
- Do not use sterilization pouches containing water-soluble adhesive components such as PVA (polyvinyl alcohol). Adhesive components washed out during sterilization may enter the product, causing problems such as poor rotation, sticking and failure to operate correctly.
- Do not heat or cool the product too quickly. Rapid change in temperature could cause damage to the product.
- For cleaning and disinfection, use disinfectant ethanol or disinfectant isopropanol that does not contain any additives (hereinafter referred to as disinfectant alcohol). Use of disinfectants other than disinfectant alcohol may cause discoloration or cracking.
  * For details, contact the manufacturer of the disinfectant.
  * In this operation manual, disinfectant ethanol or disinfectant isopropanol that does not contain any additives (any quaternary ammonium salts) is called by "disinfectant alcohol".
- Use appropriate disinfectant alcohol according to the regulations and guidelines of each country.
- Before the disinfection, be sure to clean the product to remove any residues. If blood remains in the product, it coagulates causing a malfunction of the product.
- Use clean and dry compressed air for cleaning.
- Store the product in a well ventilated place out of direct sunlight and within the range of temperature, humidity and pressure specified in specifications.
- The product lifetime and product's ability to operate correctly are mainly determined by mechanical stresses during use and the chemical influences due to processing. If you detect any abnormality such as center run-out of bur / Prophy handpiece, heat generation, vibration or noise, or if the exterior markings (serial number or model number) have become unreadable before or during use, stop using the product immediately and request your nearest NSK dealer, or one of the NSK branches for a periodic inspection*. Disappearance of exterior markings is not covered under warranty for repair. When the product has been reprocessed 250 times or has been in use for one year, it is recommended that a periodic inspection be performed by an authorized NSK service*.
  * Refer to the link below:

3–1 Pre-cleaning

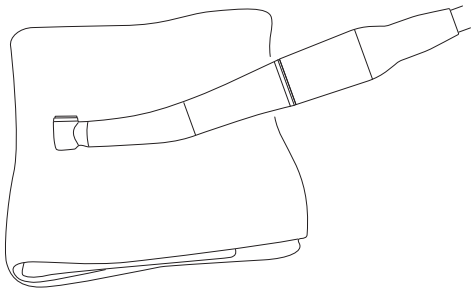
❶



❷

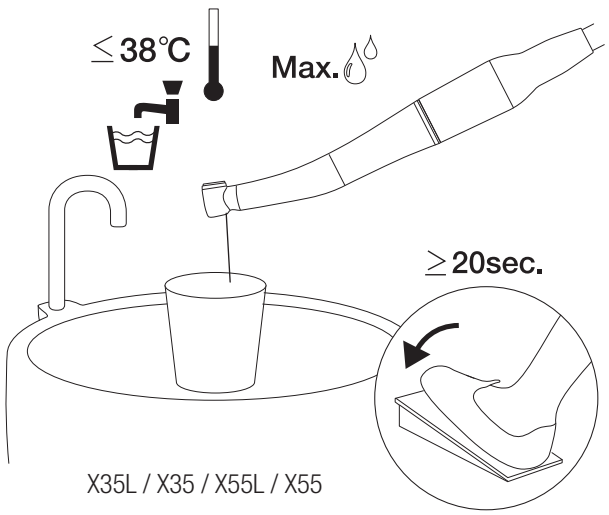


❸



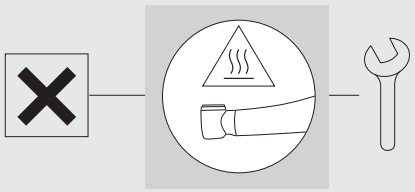
Minuten Wipes (ALPRO)

❹

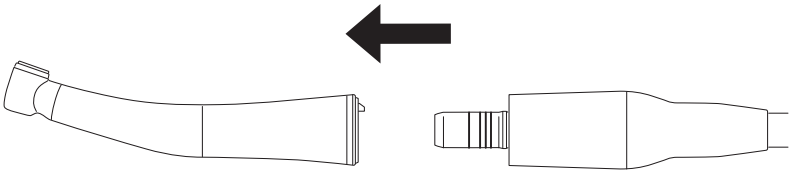


X35L / X35 / X55L / X55

⚠ CAUTION

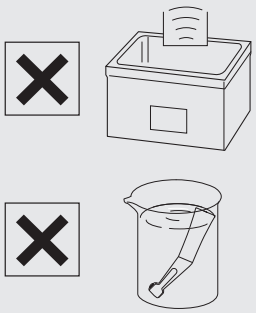


❺



⇒ 3-2-1 Manual method / 3-2-2 Automated method

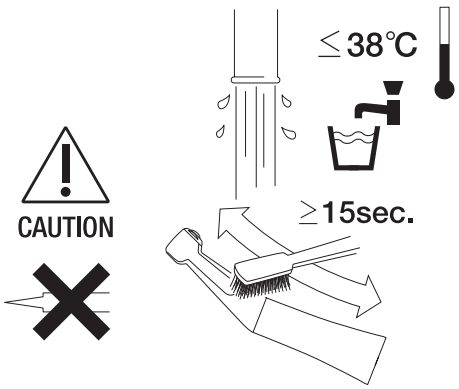
⚠ CAUTION

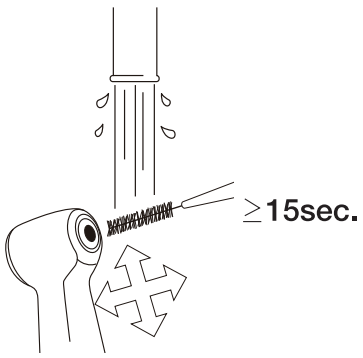


3–2 Cleaning and disinfection

3–2–1 Manual method

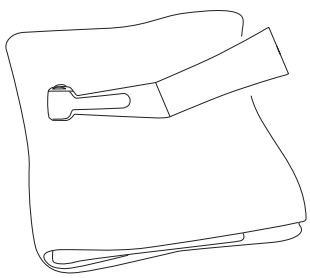
❶





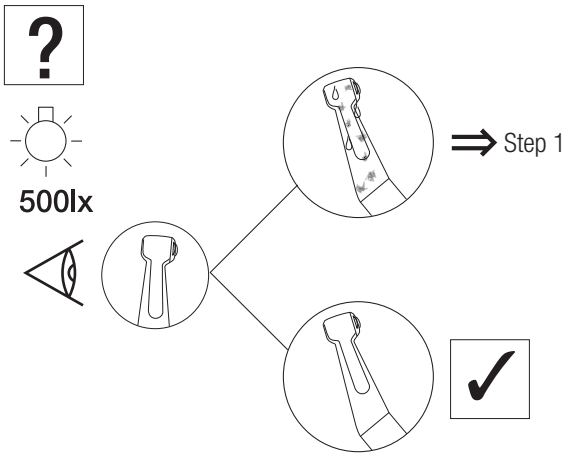
ISO 16409 size 4
(wire thickness 0.7mm)

❷



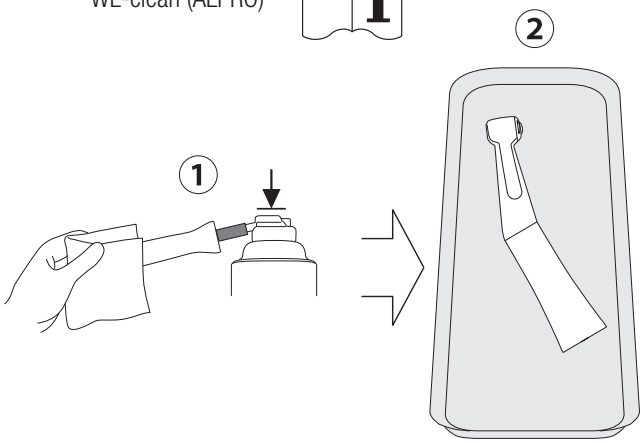
Dry Cloth

❸

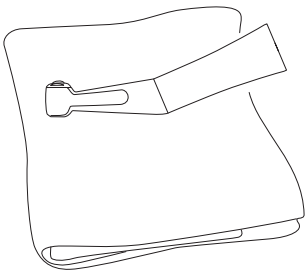


❹

WL-clean (ALPRO)



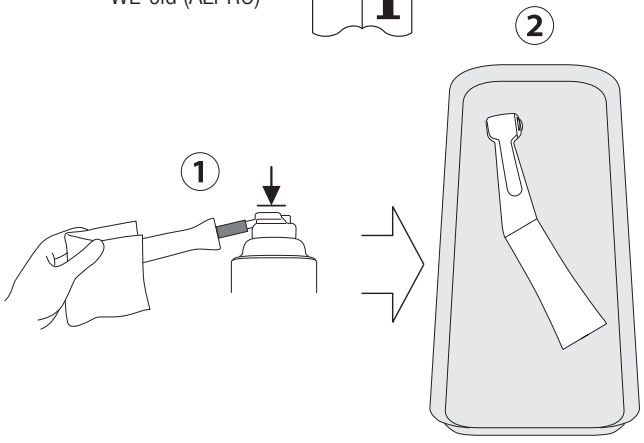
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Minuten Wipes (ALPRO)

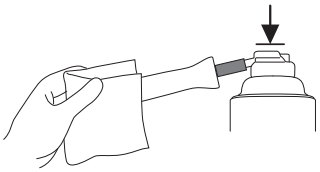
❻

WL-cid (ALPRO)

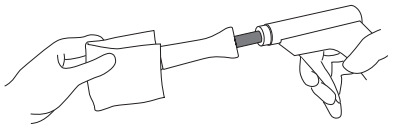


❼

WL-dry (ALPRO)



WL-blow (ALPRO)

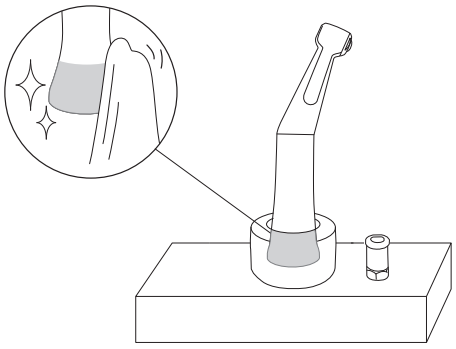


⇒ 3-3-1 Manual method / 3-3-2 Automated method

3–2–2 Automated method

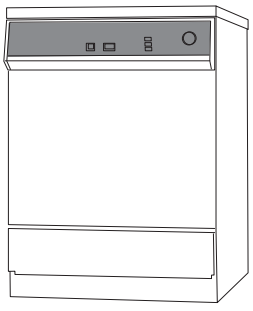
❶

Minuten Wipes (ALPRO)

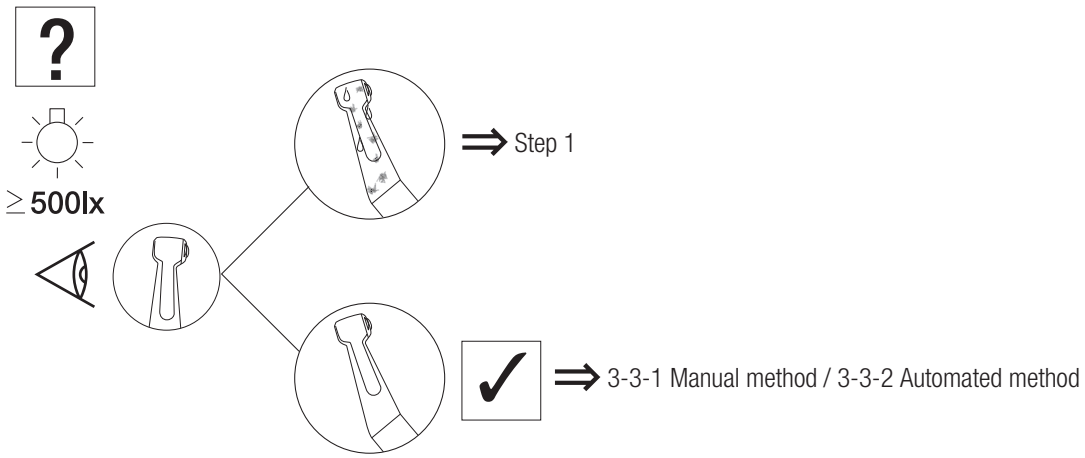


❷

ISO 15883-1
(EN ISO 15883-1)



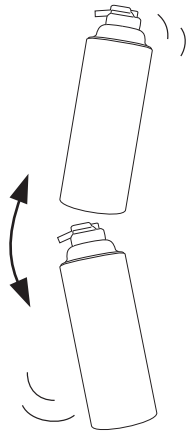
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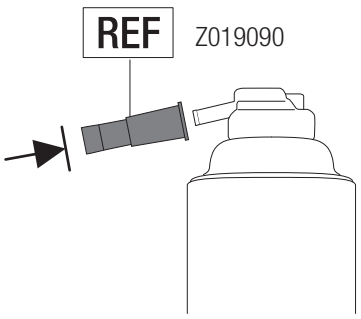
3–3 Lubrication

3–3–1 Manual method

❶

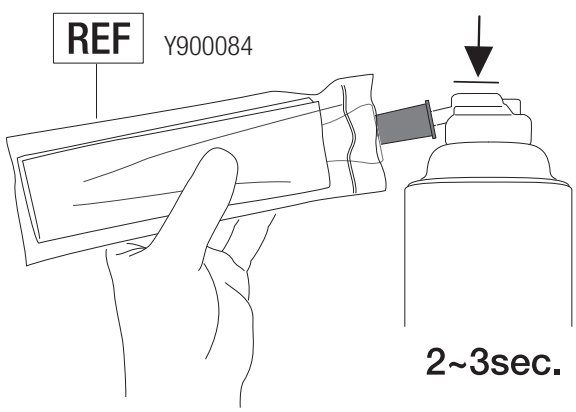


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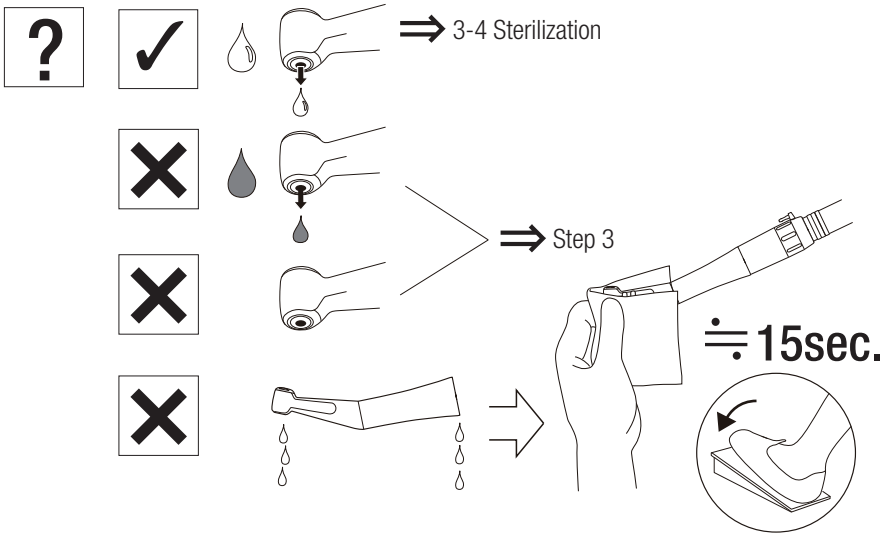
NSK PANA SPRAY Plus

❸

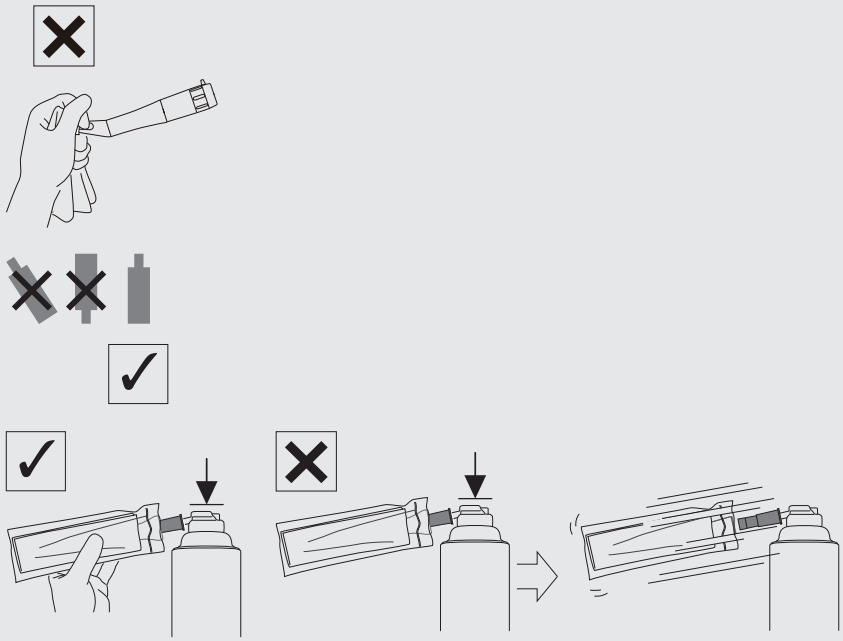


Post-use Maintenance

❹

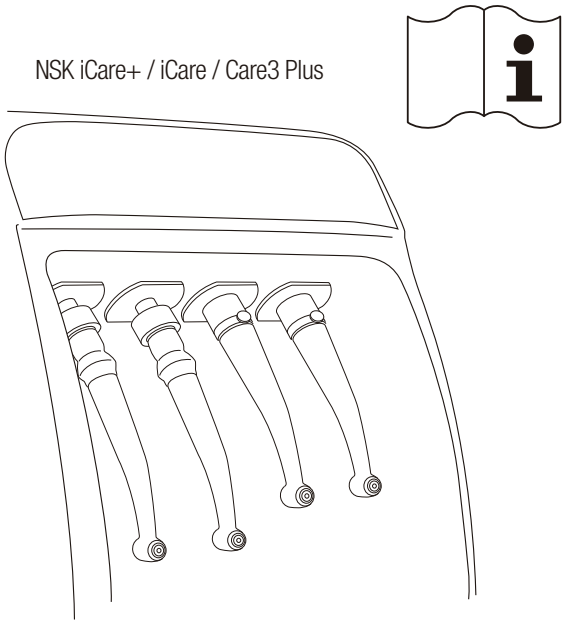


⚠ CAUTION



3–3–2 Automated method

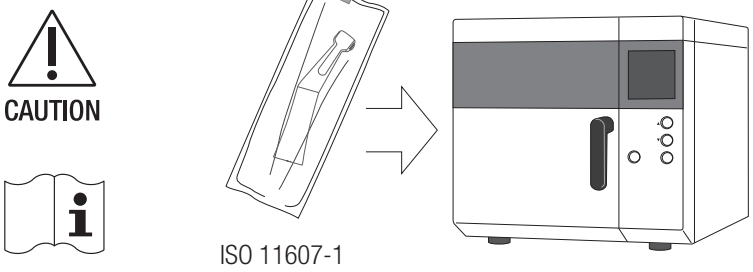
❶



⇒ 3-4 Sterilization

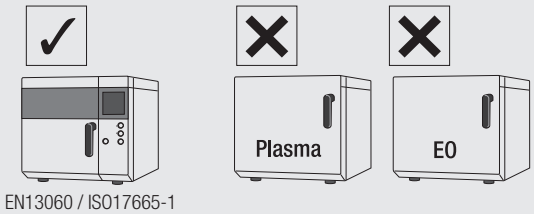
3–4 Sterilization

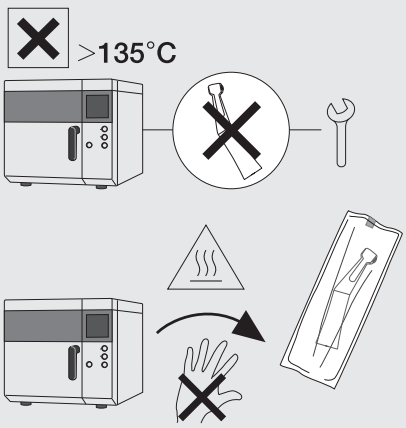
❶



	Class N	Class B
	132℃	134℃
135°c	≥15min	3-18min
	≥30min	≥30min

⚠ CAUTION

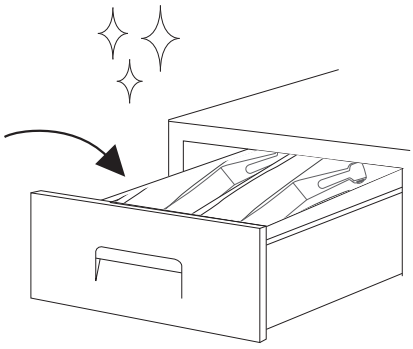




Post-use Maintenance

❷



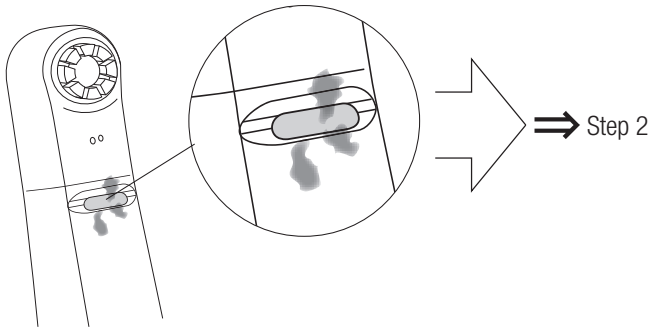


4 Maintenance

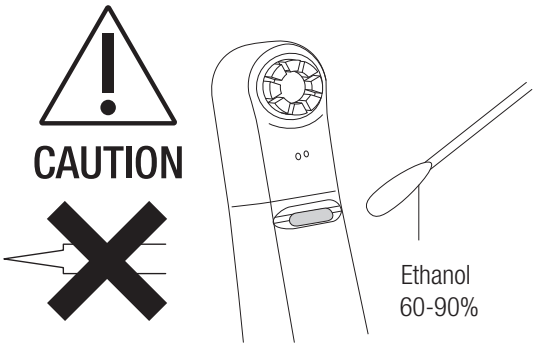
4–1 Cleaning glass rod optic end

X35L / X55L / X55 / X57L

❶



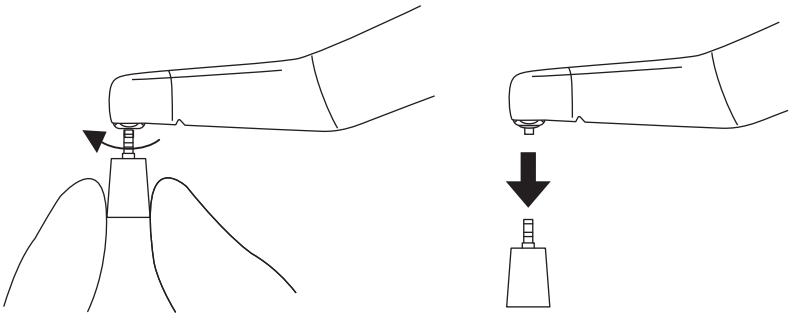
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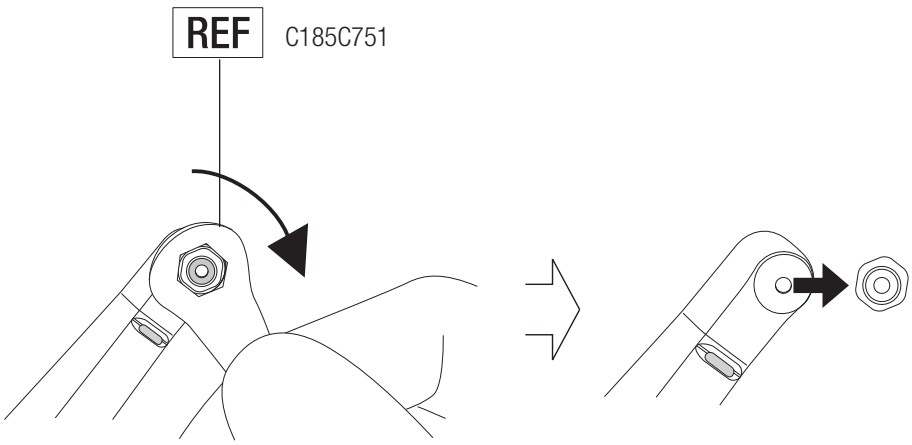
4–2 Ultrasonic cleaning

X57L / X57

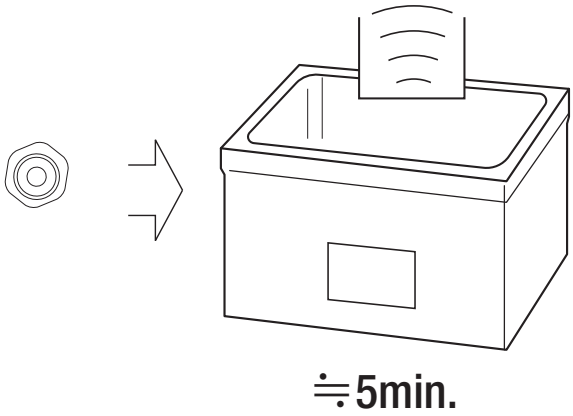
❶



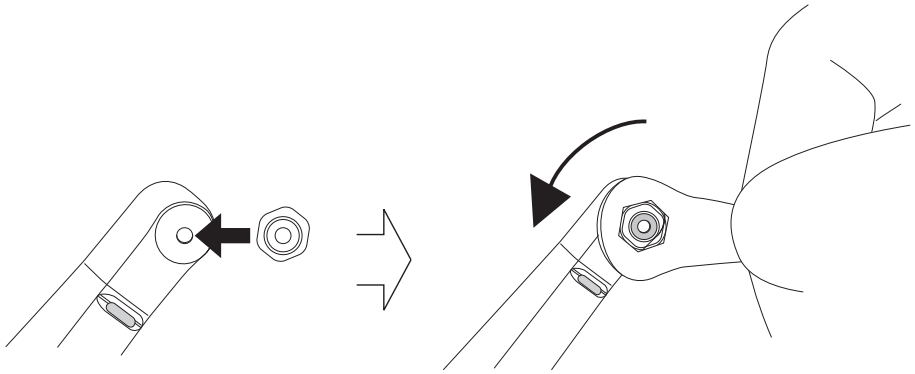
❷



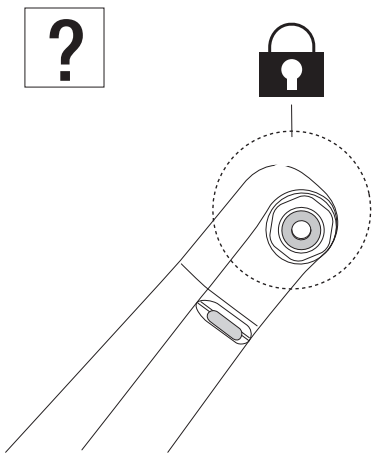
❸



❹



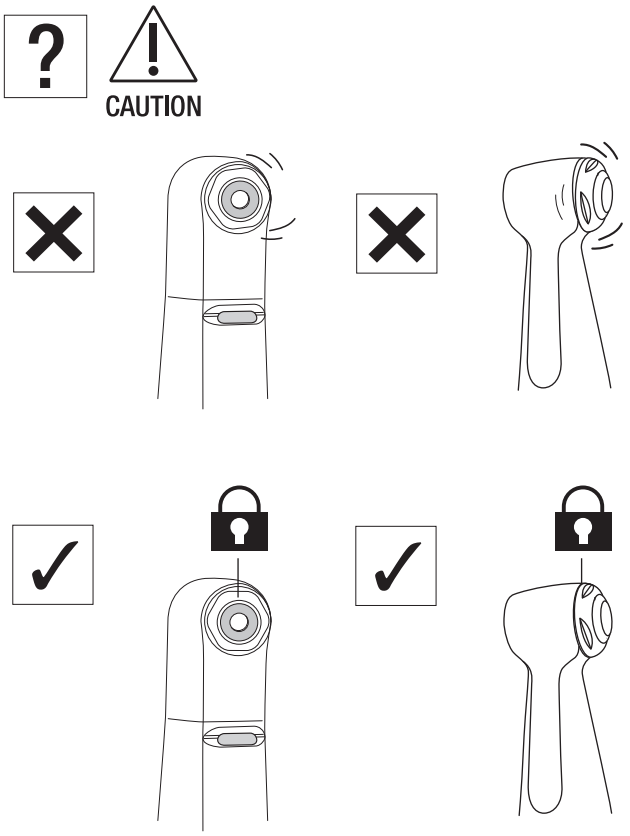
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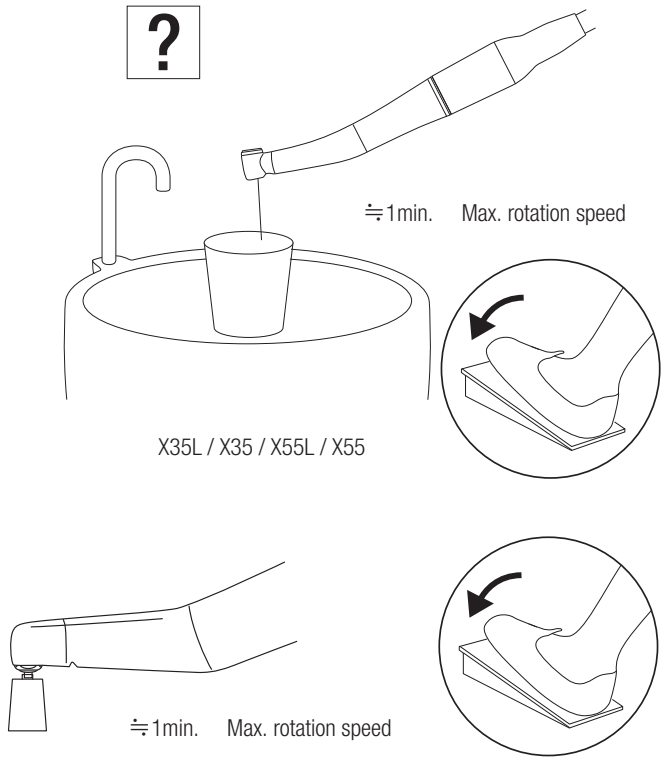
4–3 Periodical Maintenance Checks

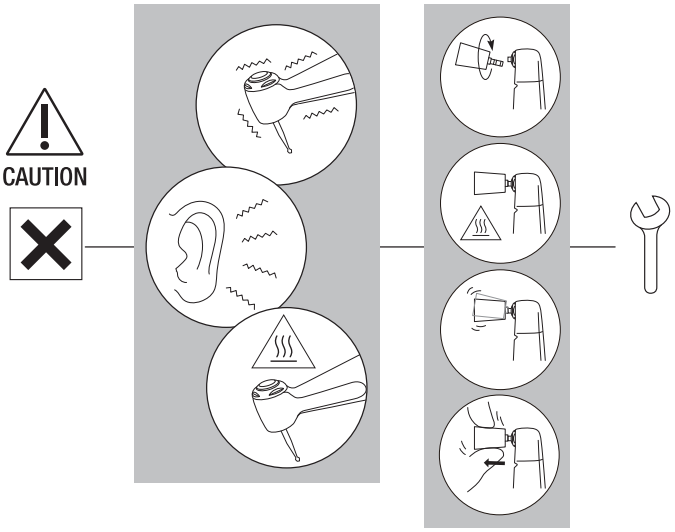
Every 3 months

❶

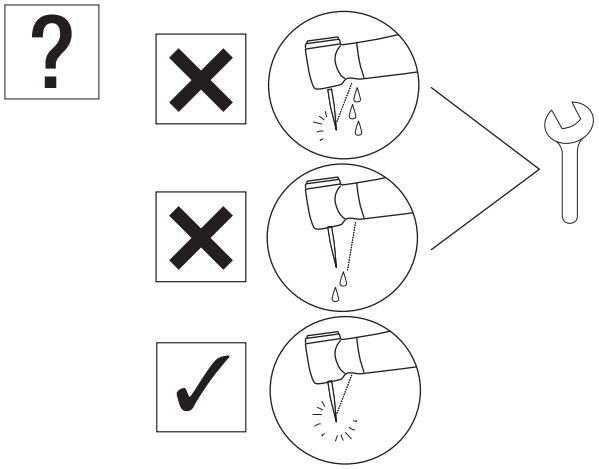


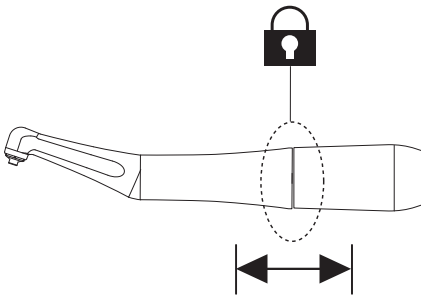
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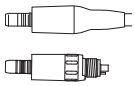
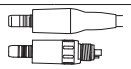
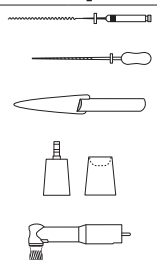
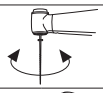
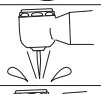
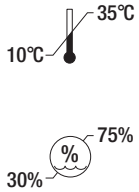
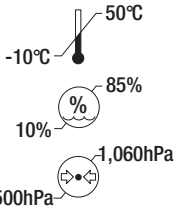


❸





5 Specifications

MODEL:	X35L	X35	X55L	X55	X57L	X57	FX75	FX75m	FX57	FX57m	FX58m	FX55m	FX74m	FX70m	FX50m
	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	
															✔
	✔	✔	✔	✔	✔	✔		✔		✔	✔	✔	✔	✔	✔
	ISO 3964 (EN ISO 3964) Type 3 ISO 3964 (EN ISO 3964) Type 2		ISO 3964 (EN ISO 3964) Type 3 ISO 3964 (EN ISO 3964) Type 2		ISO 3964 (EN ISO 3964) Type 3 ISO 3964 (EN ISO 3964) Type 2		ISO 3964 (EN ISO 3964) Type 1		ISO 3964 (EN ISO 3964) Type 1		ISO 3964 (EN ISO 3964) Type 1	ISO 3964 (EN ISO 3964) Type 1	ISO 3964 (EN ISO 3964) Type 1	ISO 3964 (EN ISO 3964) Type 1	ISO 3964 (EN ISO 3964) Type 1
 Max. rotation speed (min^{-1})	40,000		40,000		40,000		40,000		10,000		10,000	40,000	40,000	40,000	10,000
 Max. rotation speed (min^{-1})	4,000		10,000		2,500		2,500		2,500		2,500	10,000	2,500	2,500	2,500
	10:1 Reduction		4:1 Reduction		16:1 Reduction		16:1 Reduction		4:1 Reduction		4:1 Reduction	4:1 Reduction	16:1 Reduction	16:1 Reduction	4:1 Reduction
	Engine Files ISO 3630-1 (EN ISO3630-1) (Ni-Ti File) ISO 1797 Type 1 Shankø2.35mm / Hand Files ISO 3630-1 (EN ISO3630-1) Shank ø3.8-4.0		Eva Tip / Profin Tip / Orthodontics File (Shankø2.36-2.40mm) *Metallic shank cannot be used.		Screw-in prophy cup / brush ISO 13295 Type 5 M1.8×0.35		Engine Files ISO 3630-1 (EN ISO3630-1) ISO 1797 Type 1 Shank ø2.35mm		Screw-in prophy cup / brush ISO 13295 Type 5 M1.8×0.35		Snap-on prophy cup / brush	Eva Tip / Profinaaa Tip / Orthodontics File (Shank ø2.36-2.40mm) *Metallic shank cannot be used.	Engine Files ISO 3630-1 (EN ISO3630-1) ISO 1797 Type 1 Shank ø2.35mm	Hand Files ISO 3630-1 (EN ISO3630-1) Shank ø3.8-4.0	ISO 14457 (EN ISO 14457) Prophy Handpiece
	60°Twist		Vertical Reciprocating width: 1.4mm		360°Rotation		360°Rotation		360°Rotation		360° Rotation	Vertical Reciprocating width: 1.4mm	80° Twist	60° Twist	360° Rotation
	Single Spray		Single Spray		-	-	-	-	-	-	-	-	-	-	-
	0.20MPa (2.0kgf/cm^2)				-	-	-	-	-	-	-	-	-	-	-
	0.20MPa (2.0kgf/cm^2)				-	-	-	-	-	-	-	-	-	-	-
	≥50mL/min (0.20MPa)				-	-	-	-	-	-	-	-	-	-	-
	≥1.5NL/min (0.20MPa)				-	-	-	-	-	-	-	-	-	-	-
	Glass Rod	-	Glass Rod	-	Glass Rod	-	-	-	-	-	-	-	-	-	-
															
															

Specifications

MODEL:		X35L	X35	X55L	X55	X57L	X57	FX75	FX75m	FX57	FX57m	FX58m	FX55m	FX74m	FX70m	FX50m
		✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
				✔	✔								✔			
						✔	✔									

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Specifications are subject to change without notice.

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